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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,731	09/27/2005	Vesna Skulj	RG/G-32919A	3189

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EXAMINER	
KARPINSKI, LUKE E	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
03/01/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,731	SKULJ ET AL.	
	Examiner	Art Unit	
	LUKE E. KARPINSKI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-12 and 15-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-12 and 15-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/22/2010 has been entered.

Claims

Claims 2, 3, 13, and 14 are canceled.

Claims 1, 4-12, and 15-20 are pending and under consideration in this action.

Rejections

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is not clear as to what the active substance is, the examiner presumes that 'the active substance' refers to amoxicillin or clavulanic acid in claim 1 but can not determine which one applicant desires.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 20 recites: “up to about”. Either the claim is "up to" the value or it is "about" the value. ‘Up to’ provides a static point while ‘about’ provides a dynamic point with wiggle room. Therefore, it is unclear exactly what is being claimed. The court held that claims reciting “at least about” were invalid for indefiniteness where there was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term “about.” Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).

Claim 9 recites the limitation "the active substance" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1, 4-12, and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 6,194,001 to Gribbon et al. in view of the publication "Water sorption and near IR spectroscopy to study the differences between microcrystalline cellulose and silicified microcrystalline cellulose before and after wet granulation" to Buckton et al.

Applicant Claims

Applicant claims a tablet comprising amoxicillin, clavulanic acid, silicified microcrystalline cellulose (SMCC), excipients, and no disintegrants other than SMCC.

Applicant further claims amoxicillin trihydrate, potassium clavulanate, ratios and percentages of all components, hydrogenated castor oil, said tablets as orodispersible and dispersible, a process for making said tablets, and that no component undergoes granulation.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Gribbon et al. teach tablets comprising amoxicillin, clavulanic acid, and microcrystalline cellulose (MCC), and that said compositions may comprise of one or more disintegrants (abstract and col. 2, lines 46-51) as pertaining to claims 1, 15, and 16.

Gribbon et al. further teach amoxicillin trihydrate (col. 2, lines 12-13), as pertaining to claim 4, potassium clavulanate (col. 2, lines 10-11), as pertaining to claim 5, an amoxicillin to clavulanic acid ratio of 1:1 to 12:1 and 4:1 (col. 2, lines 14-18), as

pertaining to claims 6-8, 20-90% and 30% of said active present (col. 2, lines 18-20), as pertaining to claims 9 and 10, 0.1-30% disintegrant (MCC) (col. 2, lines 46-65), as pertaining to claims 10 and 11, talc as a lubricant (col. 3, lines 1-2), as pertaining to claim 12, that direct compression may be used (col. 2, lines 36-39), as pertaining to claim 18, that said formulations MAY be granulated (col. 3, lines 42-43), as pertaining to claim 19, specific amounts of active substances (examples), as pertaining to claim 20, and methods for making tablets comprising mixing components for 10 minutes, which reads on blending and homogenizing, sieving said formulations, and forming said formulations into tablets (example 3), as pertaining to claim 17..

Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)

Gribbon et al. do not teach SMCC as claimed. This deficiency in Gribbon et al. is cured by Buckton et al. Buckton et al. teach that MCC and SMCC are both used in tablet formulations and that SMCC has improved flow properties (introduction).

Further, Gribbon et al. do not teach hydrogenated castor oil as claimed in claim 12. This deficiency is cured by de Haan et al. de Haan et al. teach tablet formulations comprising hydrogenated castor oil or talc as a lubricant (col. 2, lines 42-46).

Further, Gribbon et al. do not explicitly disclose an MCC to active ratio, however, Gribbon et al. do teach percentages of each component and said ratios are found within said percentages.

Further, Gribbon et al. do not explicitly disclose that granulation is not performed, however, Gribbon et al. do teach that granulation MAY be performed, which reads on said granulation being performed and NOT being performed.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Regarding the use of SMCC, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the formulations of Gribbon et al. with SMCC as taught by Buckton et al. in order to produce the invention of the instant claims.

One of ordinary skill in the art would have been motivated to do this because Buckton et al. teach that SMCC have improved flow properties (page 42, left column). Therefore it would have been obvious to utilize the SMCC of Buckton et al., in the formulations of Gribbon et al. in order to produce a tablet with improved flow properties.

Regarding claim 12, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the formulations of Gribbon et al. with hydrogenated castor oil as taught by De Haan et al. in order to produce the invention of instant claim 12.

One of ordinary skill in the art would have been motivated to do this because Gribbon et al. and de Hann et al. both teach tablet formulations with lubricants and de Haan et al. teach that either talc or hydrogenated castor oil may be used as a lubricant

in tablets. Therefore it would have been obvious to utilize the hydrogenated castor oil of de Haan et al., in the tablets of Gribbon et al. in order to use another know lubricant.

Regarding the limitation of a ratio of SMCC to actives, Gribbon et al. teach percentages for MCC and said actives within which said ratios are found.

Regarding the limitation of no component undergoing granulation, Gribbon et al. teach that granulation MAY be performed, this reads on said granulation as optional and therefore the absence of said granulation was contemplated.

Regarding claim 20, it would have been obvious to one of ordinary skill in the art what amounts of active substances could be incorporated into a tablet.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments with respect to all claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Claims 1, 4-12, and 15-20 are rejected.

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUKE E. KARPINSKI whose telephone number is (571)270-3501. The examiner can normally be reached on Monday Friday 9-5 est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LEK

/Mina Haghighatian/
Primary Examiner, Art Unit 1616